SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING JANUARY 24, 2000

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on January 24, 2000, at 2 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues includes items from NELAC V and Vi (Attachment C). Attachment D is the updated table that logs and documents the status of comments received by the QS Committee. The purpose of the meeting was to review administrative and action items, discuss the resolution of comments received by the QS Committee, and establish future meeting dates.

ADMINISTRATIVE ITEMS

The chair discussed the low attendance at past meetings and the problem of setting future teleconference dates without full attendance.

The chair reminded the committee that replacement members will need to be selected and added this item to the "parking lot."

The chair discussed electronic mail issues and confirmed that QS members are receiving e-mail messages and attachments. Although a few members had some difficulty with some of the attachments, the committee members are receiving the electronic communications from the chair and other committee members.

Mr. Slayton requested that Ms. Sylvia Labie bring an issue to the Board of Directors; the last 6 sets of comments received by the QS committee were received electronically, but not in the correct format. The comments do not include suggested revised language.

In order to meet the deadline for posting minutes, RTI will return the draft minutes to the committee chair within 5 working days for approval. The chair will have 5 working days to review and approve the minutes before they are submitted for posting on the website. The committee also discussed providing adequate time for NELAP to review the minutes, approximately 1 or 2 days.

Ms. Lisa Doucet submitted information to the QS committee about deadlines for NELAC VI. NELAC VI will be held on June 26-29 in Williamsburg, VA. Deadlines include:

- February 14th submit to Ms. Doucet time requirements for on-site QS sessions;
- April 27th provide final changes to the NELAC standards;
- May 12th submit the agenda for NELAC VI; and
- May 12th send a letter nominating each new member for the QS committee to Dr. Pearson and ask for his concurrence. The letter should include a resume or form for each candidate. The replacement of committee members will be voted on by May 12th. The QS committee assumes that the nomination for a new chair will follow the same timing as the nomination for

committee members. The new members will not serve on the committee until after NELAC VI.

Mr. Ray Frederici will be leading a conference session on ISO standards, which will describe changes from ISO 25 to 1725. ISO 1725 has been approved. An action item for Mr. Frederici is to share his presentation with the committee when he is prepared.

ACTION ITEMS FROM JANUARY 7TH TELECONFERENCE AND PARKING LOT ISSUES

The following action items were completed by the chair since the last teleconference:

- Submit the dates and times of the next QS meetings to Lisa Doucet via e-mail;
- Update the comment "homework" table to include the six comments received from the interim meeting;
- Send the homework (i.e., the new comments) to committee members;
- Send comment #8 from the Lehigh County Authority and the committee's response to Chapter 4;
- Send the comment from Kodak (#13) concerning terms and definitions to Chapter 1; and
- Approve the draft teleconference minutes prepared by RTI.

In addition, Mr. Slayton requested input from Jeanne Hankins whether the QS committee's "guiding principles" can be a fixed, stand-alone document on the web site instead of attached to QS minutes. Ms. Hankins agreed to the recommendation. As a result, the guiding principles of the QS committee will no longer be included in the minutes.

Work Cells

The committee deferred this topic until the lead for this discussion is present. In addition, homework F will be discussed at the 2/9/00 teleconference.

Radiochemistry

The chair's goal for this discussion was to gain a clear listing of the issues. At the chair's request, Ms. Jane Jensen from California participated in this portion of the meeting.

Mr. Slayton will contact volunteers for the Radiochemical work group. Mr. Slayton will distribute Jane Jensen's comments and proposed revisions for Radiochemistry (Section D.4), which are designated as "B" on the homework table (see Attachment D). The committee agreed that two meetings would be adequate to address the issues and make subsequent proposed revisions in time for NELAC VI. Proposed changes to the standard are due April 27, 2000. The first meeting will be scheduled in late February with the expectation that the work group will have reviewed the materials in advance. A follow-up meeting will be scheduled for March. The work group will have a narrow scope given the time constraints and will restrict their discussion to addressing comments from Jane Jensen/California. The chair stated that any QS committee member that is interested may join the teleconferences. Mr. Slayton will participate in both meetings.

HOMEWORK REVIEW

The chair reviewed the homework table. There were some committee members who could not read the homework table or who did not receive the attachments. The chair will resend the information to those individuals. The next teleconference will begin with homework #14, comments received by Test America. The January 7th teleconference ended on a discussion of section 5.12.3.3, which is where the discussion will be reinitiated.

Item G, Ethics

Ken Jackson asked for more detail and specificity on ethic training, ethics, and unethical behavior. The committee discussed whether or not the standard is definitive enough (see sections 5.6.2.c3 and 5.6.2.h). The standard was purposefully left broad as it is not NELAC's job to develop a code of ethics. NELAC considers it the responsibility of the organization to develop their own ethics program. Auditors will look for an ethics program that includes a prevention system and a training program, but will not address the content of the training. The committee agreed that the standard should remain general, but the committee is proposing a change which will clarify that laboratories develop their own program and code of ethics in Section 5.5.2U.

The commenter will work with his labs to resolve the issue. The QS committee provided information to the commenter on ethics training.

COMMENTS FROM NELAC Vi

The chair requested that the discussion begin with Section D.5, Air Testing and requested that QS committee members bring their notes from the NELAC Vi. The committee identified an action item for the chair: replace the 6/26/99 version of the air section in the next Chapter 5 update with the version that was distributed at NELAC Vi.

General

The format and numbering needs to be corrected.

The sections on surrogates, matrix spikes, analytical variability/reproducibility, matrix spike duplicates, method evaluation, demonstration of capability, calibration, and proficiency test samples had no comments.

Section D.5.1.a.1 Method Blanks

Comments from the interim meeting included provide a better definition of batch in the first sentence and broaden the last sentence beyond ambient background. The committee proposed the following:

Method Blanks - Shall be performed at a frequency of at least one (1) per batch of twenty (20) environmental samples or less <u>per sample preparation</u>...If the source of the contamination is found to be ambient background, the data will be qualified in the report.

Section D.5.1.a.2 Break Through

This section will be revised and titled "collection efficiency" and will be specific to commercial sorbent tubes with multiple sections. Proposed language is being commented on among the committee.

Section D.5.1.b.i Laboratory Control Samples

Laboratory Control Samples - Shall be analyzed at a rate of one (1) per batch of twenty (20) or fewer samples for each analyte <u>per sample preparation</u>. If a spiking solution is not available, a calibration solution whose concentration approximates that of the samples, shall be <u>including included</u> in each batch <u>and each lot of media.</u> If the target analyte concentrations are above the calibration midpoint, the LCS <u>should</u> be above the calibration midpoint <u>shall</u> be relevant to the <u>intended use of the data either at or below the regulatory level</u>. If the target analyte concentrations are below the calibration midpoint, the LCS <u>should</u> <u>shall</u> be below the calibration midpoint...

Section D.5.b.2 Desorption Efficiency (Recovery)

The comment was made on this section that as long as control samples are run on preparation batches, then this is not needed.

Section D.5.4 Detection Limits

The committee agreed that detection limits need to relate to the concentration of interest. An action item was added to look at the definition of detection limits in the glossary and develop a definition consistent with the text in this section.

QS TELECONFERENCE SCHEDULE

The committee scheduled two teleconferences in March in addition to confirming the two February teleconferences that were scheduled at the previous meeting.

Wednesday, February 9th
Wednesday, February 23rd
Monday, March 6th
1-3 p.m. (Eastern)
1-3 p.m. (Eastern)

Wednesday, March 22nd 1-3 p.m. (Eastern)

ACTION ITEMS QUALITY SYSTEMS COMMITTEE MEETING JANUARY 24, 2000

| Item No. | Action Item | Date to be Completed |
|----------|--|-------------------------|
| 1. | Mr. Slayton will submit the dates and times of the next QS meetings to the WIC and Lisa Doucet via e-mail. | January 31, 2000 |
| 2. | Mr. Slayton will add the glossary to the agenda for the next teleconference. In addition, consider consistency of detection limits definition in glossary and section D.5.4. | January 31, 2000 |
| 3. | Ms. Boshes will prepare the draft minutes of the teleconference and submit them to Mr. Slayton. | January 31, 2000 |
| 4. | Update the version of D5 in the next Chapter 5 revision to replace the 6/26/99 version. | January 31, 2000 |
| 5. | Ms. Labie will inform the Board that the last 6 sets of comments for the QS committee were received electronically, but not in the correct format. The comments do not include suggested revised language. | February 14, 2000 |
| 6. | Mr. Ray Frederici will share his presentation with the QS committee on ISO standards describing changes from ISO 25 to 1725. | TBD |
| 7. | Submit on-site QS session time requirements for NELAC VI to Ms. Doucet | February 14, 2000 |
| 8. | Provide final changes to the NELAC standards. | April 27, 2000 |
| 9. | Submit the agenda for NELAC VI. | May 12, 2000 |
| 10. | Send nominating letter for each new member for the QS committee to Dr. Pierson including a resume or form for each candidate. The replacement of committee members will be voted on by May 12. The nomination for a new chair will follow the same schedule. | May 12, 2000 |

PARTICIPANTS QUALITY SYSTEMS COMMITTEE JANUARY 24, 2000

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|---|---|---|
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PARKING LOT ITEMS/ISSUES Quality Systems Committee

Items/issues will remain in the Parking Lot until they are completed. Items three and four were added to the parking lot following the January 7, 2000 meeting.

- 1. Review terms in Chapter 5 for terms needing clarification, e.g., "such as," "independent standard," "alternate source," "second" or "alternate source."
- 2. Combine "Analyst Training" and "Verification" into same section.
- 3. Select replacement members for the QS committee. Nomination letters are due by May 12th, 2000.
- 4. Standard and Comments on Appendix D, Section D.1.1.b1 & D.1.1.b2 (NELAC July 1999) (See Attachment G.)

Current Standard:

Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix per sample extraction or preparation method... ...NOTE: the matrix spike (see 2 below) may be used in place of e of this control as long as the acceptance criteria are as stringent as for the LCS.

Comments submitted by Kodak:

- 1) It is not clear from the wording in these two paragraphs which frequency would take precedence when matrix spikes are used instead of LCS, LCS, which includes the batch criterion, or MS, which does not include a batch specification.
- 2) If the wording I proposed in Section 5.1.b were to be approved, the USEPA Program objectives, as laid down in the approved method, would take precedence over the requirement in paragraph D.1.1.b)1). I think this is appropriate; USEPA and NELAC must maintain a sensitivity to the balance between mandating quality control requirements and the cost to the regulated community to perform the analysis.

EXAMPLE: Method 625 requires QC Check Samples to be run only if the Matrix Spike analysis fails to meet acceptance criteria. Matrix Spikes are specified at a 5% frequency, same as Section D.1.1.b)2). In the case of my laboratory and my company's permitted discharge, we are required to take 1 sample for Method 625 analysis on an 8-day cycle. We also take an influent sample to our treatment plant, so we actually have 2 samples per 8-day cycle. We use a turnaround time of 7 days (customer requirement). We therefore 'batch' the preparation of the two samples one day per week. If we were required to prepare an LCS for each 'batch', our sample load for the test would increase by approximately 40% (considering the monthly/every 20 matrix spike), as would the discharge of extraction solvents (methylene chloride - a presumed carcinogen) to the atmosphere. Note: We make a point of analyzing a spiked blank as an LCS along with our matrix spikes to assure that there is always a QC Check Sample available for evaluation in the event of a Matrix Spike failure.

3) It should be made clear that the LCS, when used for batch acceptance, is tied to the sample preparation batch, not necessarily the instrument analytical batch. It is very common (in metals analysis, for example) to have multiple days' digestions queued to run on an ICP in the same analytical batch. The LCS should only be evaluated against the samples with which it was prepared. Note that for some methods such as Method 624, there is not a distinction between preparation and analytical batches, because the preparation is part of the instrument analytical process.

Comment 4) I would assume, but it is not stated, that the LCS must have all analytes present for a multi-analyte method such as ICP or 625. In this case, the allowance for using the matrix spike results would seem to introduce a potential inconsistency for those methods which specifically allow or state a subset of analytes for matrix spikes. In any event, the LCS in a method such as 625 is critical for evaluating the performance of the analytical system in the event of matrix spike failure (as required in the method). I therefore don't think this exception (matrix spike substituted for LCS) is appropriate.

Comment 5) Since the LCS is a quality control sample used primarily for assessing the preparation of a sample batch, allowance/consideration should be made for methods which have built-in verification of the quality of the sample preparation - i.e. surrogates.

5. Standard and Comments on Section #: 5.9.4.2.2 b (NELAC July 1999). (See Attachment G.)

Current Standard:

b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range...

Comments submitted by Kodak:

Please refer to my comments and recommended change for Section 5.1b). A case in point: Method 200.7 has specific requirements (varying by the published version) for the concentrations to be used in the LPC/IPC solution, which is, in my interpretation, a CCV. This solution is required to be analyzed after every 10 samples and at the end of the batch. One could argue that the requirement in this section of the standard to vary the concentration of the CCV is "more stringent" than that of 200.7. To be compliant with program requirements, the specific version of Method 200.7 must be followed. What value would be added to the quality of data by requiring at least one (and presumably two, if the concentrations are to be truly varied) more CCV at the beginning or end of the run to satisfy the requirements of this section?

Note also that Standard Methods, which is used as an authoritative source for many State programs, specifies in Section 3020 of the 18th edition that a midpoint standard be run for the CCV. One (hopefully temporary) effect of requiring varying concentrations for the CCV is that NELAP-approved laboratories that must also adhere to non-NELAC State programs will be required to run both midpoint and varying concentrations of CCVs.

EXAMPLE: We were running an analysis for Silver by Method 272.1, and running a CCV of 1mg/L, with a calibration range up to 4 mg/L. We were told by a state auditor that we must change the CCV concentration to 2 mg/L, even though we had chosen the 1 mg/L standard because it is a typical action level for our customers. Requiring that the CCV be varied in concentration would not really add value to the analysis for these customers, and requiring a midpoint standard actually decreases the value when considered against their action limits.